

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	3
-------	---	----	---

Complete if Known

Application Number	09/867,693
Filing Date	May 31, 2001
First Named Inventor	Cooper, et al.
Group Art Unit	1646
Examiner Name	Unassigned
Attorney Docket Number	003659.00009

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

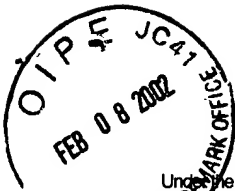
Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

USPTO Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	09/867,693
Filing Date	May 31, 2001
First Named Inventor	Cooper, et al.
Group Art Unit	1646
Examiner Name	Unassigned
Attorney Docket Number	003659.00009

TECH CENTER 600/2900

RECEIVED

FEB 11 2002

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
Dr		Aberle, et al., "The counterion influence on cationic lipid-mediated transfection of plasmid DNA", Biochimica et Biophysica Acta, 1996, pages 281-283, Elsevier Science B.V.	
		Allison, et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", Journal of Pharmaceutical Sciences, 2000, pages 682-691, vol. 89, no. 5, Wiley-Liss, Inc., & American Pharmaceutical Association.	
		Choi, et al., "Lactose-Poly (ethylene Glycol)-Grafted Poly-L-Lysine as Hepatoma Cell-Targeted Gene Carrier", Bioconjugate Chem., 1998, pages 708-718, vol. 9, American Chemical Society.	
		Cortesi, et al., "Effect of DNA Complexion and Freeze-Drying on the Physicochemical Characteristics of Cationic Liposomes", Antisense & Nucleic Drug Development, 2000, pages 205-215, vol. 10, Mary Ann Liebert, Inc.	
		Katayose, et al., "Remarkable Increase in Nuclease Resistance of Plasmid DNA through Supramolecular Assembly with Poly (ethylene glycol)-Poly (L-lysine)", Journal of Pharmaceutical Sciences, 1998, vol. 87, no. 2, American Chemical Society and American Pharmaceutical Association.	
		Katayose, et al., "Water-Soluble Polyion Complex Associates of DNA and Poly (ethylene glycol)-Poly (L-lysine) Block Copolymer", Bioconjugate Chem., 1997, pages 702-707, American Chemical Society.	
		Kilcher, et al., "Influence of the DNA Complexation Medium on the Transfection Efficiency of Lipopolymer/DNA Particles", Gene Therapy, 1998, pages 855-860, vol. 5, MacMillan Press LTD., Basingstoke, Great Britain.	
		Kwok, et al., "Strategies for Maintaining the Particle Size of Peptide DNA Condensates Following Freeze-Drying", International Journal of Pharmaceutics, 2000, pages 81-88, vol. 203, no. 1-2, Elsevier Science B.V.	
		Li, et al., "Lyophilization of Cationic Lipid-Protamine-DNA (LPD) Complexes", Journal of Pharmaceutical Sciences, 2000, pages 355-364, vol. 89, no. 3, Wiley-Liss, Inc., & American Pharmaceutical Association.	
		Noel, et al., "High Compacted DNA - Polymer Complexes Via New Polynorbornene Polycationic Latexes With Acetate Counterion", SCISEARCH Database, 2000, pages 8980-8983, vol. 16, no. 23, American Chemical Society, Washington, D.C.	
		Poxon, et al., "The Effect of Lyophilization on Plasmid DNA Activity", Pharmaceutical and Development Technology, 2000, pages 115-122, vol. 5, no. 1, Marcel Dekker, Inc.	

Examiner
Signature

Doh

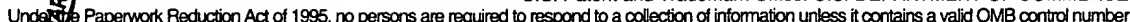
Date
Considered

1/7/03

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet	3	of	3
-------	---	----	---

Complete if Known

Application Number	09/867,693
Filing Date	May 31, 2001
First Named Inventor	Cooper, et al.
Group Art Unit	1646
Examiner Name	Unassigned
Attorney Docket Number	003659.00009

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

TECH CENTER 1600/2900₁

Pat

117103

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	09/867,693
Filing Date	May 31, 2001
First Named Inventor	Mark J. Cooper
Group Art Unit	NOT YET ASSIGNED
Examiner Name	NOT YET ASSIGNED
Attorney Docket Number	03659.00009

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
DM		ABERLE et al., The counterion influence on cationic lipid-mediated transfection of plasmid DNA, Biochimica et Biophysica Acta, 1996, 1299:281-283.	
		VINOGRADOV et al., Self-Assembly of Polyamine-Poly(ethylene glycol) Copolymers with Phosphorothioate Oligonucleotides, Bioconjugate Chem., 1998, Vol. 9, No. 6, 805-812.	
		TONCHEVA et al., Novel vectors for gene delivery formed by self-assembly of DNA with poly(L-lysine) grafted with hydrophilic polymers, Biochimica et Biophysica Acta, 1998, 1380:354-368.	
		CHOI et al., Lactose-Poly(ethylene Glycol)-Grafted Poly-L-Lysine as Hepatoma Cell-Targeted Gene Carrier, Bioconjugate Chem., 1998, Vol. 9, No. 6, 708-718.	
		KATAYOSE et al., Water-Soluble Polyion Complex Associates of DNA and Poly(ethylene glycol)-Poly(L-lysine) Block Copolymer, Bioconjugate Chem., 1997, Vol. 8, No. 5, 702-707.	
		KATAYOSE et al., Remarkable Increase in Nuclease Resistance of Plasmid DNA through Supramolecular Assembly with Poly(ethylene glycol)-Poly(L-lysine) Block Copolymer, Journal of Pharmaceutical Sciences, February 1998, Vol. 87, No. 2, 160-163.	
		KWOK et al., Strategies for maintaining the particle size of peptide DNA condensates following freeze-drying, International Journal of Pharmaceutics, 2000, Vol. 203, 81-88.	
		BEI et al., Lyophilization of Cationic Lipid-Protamine-DNA (LPD) Complexes, Journal of Pharmaceutical Sciences, March 2000, Vol. 89, No. 3, 355-364.	
		ALLISON et al., Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization, Journal of Pharmaceutical Sciences, May 2000, Vol. 89, No. 5, 682-691.	
		CORTESI et al., Effect of DNA Complexation and Freeze-Drying on the Physicochemical Characteristics of Cationic Liposomes, Antisense & Nucleic Acid Drug Development, 2000, Vol. 10, 205-215.	
		PAXON et al., The Effect of Lyophilization on Plasmid DNA Activity, Pharmaceutical Development and Technology, 2000, Vol. 5, Issue 1, 115-122.	

Examiner
Signature

Dahn

Date
Considered

1/7/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

Complete if Known

Application Number	09/867,693
Filing Date	May 31, 2001
First Named Inventor	Mark J. Cooper
Group Art Unit	NOT YET ASSIGNED
Examiner Name	NOT YET ASSIGNED
Attorney Docket Number	03659.00009

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.